UNITED STATES DISTRICT COURT DISTRICT OF NORTH DAKOTA EASTERN DIVISION

JESSICA KRAFT, individually and as parent of minors L.K., S.K., and O.K.; SHELLI SCHNEIDER, individually and as parent of minors A.S and W.S.; ANNE BAILEY, as parent of minor D.B.; AMY LAVELLE, as parent of minors Em.L. and El.L; ELIZABETH BEATON, individually and as parent of minor M.B.; AMANDA AND TYRELL FAUSKE, individually and as parents of minors C.R.F and C.J.F.; JENNIFER REIN, individually; and JESSICA BERG, as parent of minors A.B. and S.B., individually and on behalf of all others similarly situated,

Civil File No.: 3:20-cv-00121-PDW-ARS Hon. Peter D. Welte Mag. J. Alice R. Senechal

ESSENTIA HEALTH AND INNOVIS HEALTH, LLC'S SUPPLEMENTAL BRIEFING REQUESTED BY OCTOBER 4, 2024 ORDER

Plaintiffs,

VS.

ESSENTIA HEALTH, INNOVIS HEALTH, LLC d/b/a ESSENTIA HEALTH, DAKOTA CLINIC PHARMACY, LLC, JOHN DOE MANUFACTURERS, and JOHN DOE DISTRIBUTOR,

Defendants.

INTRODUCTION

Despite being protected by the Health Insurance Portability and Accountability Act ("HIPAA"), not being relevant to this lawsuit and otherwise being unduly burdensome and not proportional to the needs of the case, Plaintiffs seek an order directing Defendants, Essentia Health and Innovis Health, LLC d/b/a Essentia Health West (collectively,

"Essentia"), to produce all date/month of service designations and provide unredacted Medical Record Numbers ("MRNs") for each member of the putative class. The Court should deny Plaintiffs' request.

First, date/month of service designations are not relevant to the claims or defenses in this litigation, as Plaintiffs contend, because this information will not enable Plaintiffs to identify a particular medication stored at DCP on a particular date or at a particular temperature. Despite Plaintiffs' arguments to the contrary, it does not stand to reason that Essentia should be required to produce protected health information ("PHI") of the putative class members, particularly when that information is protected under HIPAA and Plaintiffs failed to demonstrate a legitimate need for this information in the context of this litigation. Simply put, production of this information would be grossly disproportionate when balancing the obvious cost to the provider-patient relationship and the privacy rights of the putative class members with the irrelevancy of this information to the claims and defenses at issue in this action.

Second, Plaintiffs seek unredacted MRNs for each member of the putative class. Producing this information is not proportional to the needs of the case in light of numerous financial spreadsheets that have already been produced that detail unique account identifiers, CPT codes, medications, vaccinations (and revaccinations), and financial data for the entire putative class. In addition, Essentia is not withholding production of documents entirely because they contain MRNs. Instead, Essentia has produced and will continue to produce documents that contain MRNs subject to appropriate redactions consistent with HIPAA's deidentification procedures. Plaintiffs have not demonstrated a

compelling need for this information, particularly in light of the requested data's relevance and other documents produced thus far in discovery. For these reasons, Essentia respectfully requests the Court deny Plaintiffs' requests.

PROCEDURAL BACKGROUND

Following the Special Master's Report and Recommendation concerning an *in camera* review of documents Essentia claimed privilege over (Dkt. No. 25), Essentia filed a response to the Special Master's Report and Recommendation that proposed, among other things, to produce documents subject to the medical patient privilege in redacted form. (Dkt. No. 260). Relevant to this dispute, Essentia proposed redacting date/month of service and MRNs from any documents containing such information for members of the putative class, which Plaintiffs object to. (Dkt. No. 262). A status conference was held on September 13, 2024 with the Court to discuss these issues in light of the Special Master's Report and Recommendation. At that status conference, the Court directed the parties to meet and confer over these issues and set a subsequent status conference for October 4, 2024. The parties met and conferred as directed, and, as indicated it would, Essentia internally evaluated the feasibility of overlaying unique patient identifiers over class members' MRNs.

When it became clear that providing unique patient identifiers was not feasible across the entirety of document production in this case, Essentia proceeded to redact date/month of service and MRNs and began production of otherwise responsive documents, consistent with the Special Master's Report and Recommendation. At the October 4, 2024 status conference, the Court heard arguments for and against producing

documents with date/month of service and MRNs visible to Plaintiffs and ordered additional briefing on this issue. On September 11, Plaintiffs filed supplemental briefing in support of their positions. (Dkt. No. 276). This response follows.

ARGUMENT

I. LEGAL STANDARD

Parties are entitled to liberal discovery regarding "any matter, not privileged, which is relevant to the subject matter involved in the pending action." FED. R. CIV. P. 26(b)(1). A discovery request is relevant unless the information sought can have no possible bearing on the claims or defenses of the case. See Lynch v. Experian Info. Sols., Inc., 569 F.Supp.3d 959, 963 (D. Minn. 2021) (citations omitted). However, in addition to being relevant, Federal Rule of Civil Procedure 26 mandates that the discovery sought also be "proportional to the needs of the case." FED. R. CIV. P. 26(b)(1). Factors relevant to the proportionality inquiry include "the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." *Id.* Moreover, the Court can limit the extent of discovery where the information sought can be obtained from some other source that is more convenient, less burdensome, or less expensive. See FED. R. CIV. P. 26(b)(2)(C)(i).

II. DATES OF SERVICE ARE NOT RELEVANT TO PLAINTIFFS' STATED NEEDS.

Date/month of service are only relevant if they bear on the claims or defenses of the case. *Lynch*, 569 F.Supp.3d at 963. Here, Plaintiffs argue that the date/month of service *may* be relevant to "whether the time- and temperature-sensitive medications delivered to patients were affected by the temperature excursion." Dkt. No. 274, at 4. They also argue this information is relevant to "juxtapose[e] . . . the dates class members received medications versus when Essentia knew or should have known of the temperature excursions as well as the representations that Essentia made to patients or their providers at particular points in time regarding the medications and service." *Id.* As Essentia argued at the October 4th status conference, neither of these stated reasons makes the date/month of service relevant such that disclosure of this information is necessary.

A. Dates of Service Will Not Enable Plaintiffs to Identify Whether a Particular Patient Received a Potentially Affected Medication or Vaccine.

Plaintiffs operate under the misguided notion that obtaining the date/month of service may be relevant to whether a particular patient received a medication or vaccine potentially affected by a potential temperature excursion. *See* Dkt. No. 274, at 4. This is not the case. To the contrary, production of the date/month of service for administration of potentially impacted medications and vaccines does not serve to achieve Plaintiffs' intended purpose any more than the information already produced in discovery does.

For context, Essentia terminated DCP's pharmaceutical management services, effective February 28, 2020. In anticipation of this termination, two refrigerators were

moved from DCP to an Essentia location. The temperature range was monitored by Essentia as part of this transition, during which time the temperature fell below a certain threshold. Essentia contacted DCP in follow-up and requested the temperature logs maintained by DCP. DCP denied that there had been any problems with the refrigerators or that any product had frozen. These temperature logs were produced in the very early stages of this litigation.

As Plaintiffs know, the DCP temperature logs were not complete. *See, e.g.,* Second Am. Class Action Compl., Dkt. No. 119, ¶¶ 172-182. While there is no concession that any of the vaccinations and/or medications stored by DCP between September 2017 and February 2020 were indeed exposed to a temperature excursion, patients were provided notification of a potential temperature excursion and offered revaccination at no cost out of an abundance of caution. Because these temperature logs were not complete, there is no way to definitively state one way or the other that any of the stored products were actually subjected to a temperature excursion.

In discovery, however, Essentia did produce details regarding products stored at DCP between September 2017 and February 2020, including generic and brand names, as well as manufacturer information. Over the course of this litigation, Essentia has supplemented this discovery to include voluminous de-identified financial data to include year of service, CPT Codes, procedure names, ICD Codes, administration, office visit, and CAM medication charges, as well as lot numbers where available, among other data, both for the population potentially impacted by the temperature excursion and those that received free revaccination. The practical reality is, however, that even if the date/month

of service were disclosed as Plaintiffs request, this data adds no value to the discovery already provided because there is no way to discern from this information that a particular patient received a particular medication or vaccination stored by DCP on a particular date at a particular temperature which would constitute a temperature excursion.

Because the date/month of service is not relevant to whether the time- and temperature-sensitive medications delivered to patients were actually affected by any temperature excursion, Plaintiffs' request for such information should be denied.¹

В. **Plaintiffs** Already **Possess** Sufficient Information Create Demonstratives.

Plaintiffs next argue that the date/month of service may be relevant to juxtapose dates that class members received notifications against when Essentia knew or should have known of the temperature excursions as well as representations made to patients or providers at certain points in time. *Id.* This is a red herring, as Essentia produced relevant, non-privileged documents concerning notifications, discovery of the potential temperature excursion, and representations made to Plaintiffs and the putative class, as well as the year each service was performed for each patient. Plaintiffs also ignore the fact that the relevant time period spans several years, meaning services were rendered well before Essentia had any knowledge of a potential temperature excursion at DCP and, accordingly, any notice or representations were transmitted by Essentia to its patients. Date/month of service is not

¹ Plaintiffs incorrectly assert that Essentia "does not dispute that the dates and times are relevant to the parties' claims and defenses," as this was precisely what was argued at the October 4 status conference when it was stated there was "no way to use [the date/month of service] to tie it to any of the affected products in the first place." See Dkt No. 274-1, at 10:4-24.

relevant in light of the duration of the potential temperature excursion when compared with Essentia's discovery of the same and subsequent patient notifications.

C. Essentia is not using the date/month of service as a Sword and Shield.

Plaintiffs next allege that Essentia is attempting to use the date/month of service as both a sword and shield. *Id.* at 4-5. Plaintiffs appear to confuse the relevancy of this information with its own burden of proof. Plaintiffs accurately point out that Essentia preserves all rights to raise any defense available to it in this lawsuit and will hold Plaintiffs to their burden of proof, but the date/month of service is not relevant to rebut any such defenses for the reasons articulated in Section IV(A): this information does not enable Plaintiffs to know whether a patient received a potentially affected medication or vaccine any more so than discovery already produced in this case.

D. Poor Recordkeeping did not Result in the date/month of service becoming irrelevant to the claims or defenses in this litigation.

Plaintiffs next accuse Essentia of poor recordkeeping and argue they should not be punished for Essentia's alleged conduct. *See* Dkt. No. 274, at 5-6. Plaintiffs also argue that the purported usefulness of the date/month goes to weight and not relevance. *Id.* Plaintiffs' arguments and supporting case law are inapposite to the issue at hand.

Nothing supports disclosure of the date/month of service in light of the facts of this case. Plaintiffs allege that Essentia's record-keeping was so messy that Plaintiffs will not be able to connect the medications that putative class members received on particular dates with the dates of the potential temperature excursion. *See* Dkt. No. 274, at 5-6. Plaintiffs misconstrue Essentia's argument. Essentia is not stating that the evidence Plaintiffs seek

exists but is too difficult to ascertain; instead, the information Plaintiffs seek does not generally exist. Because that information does not exist, the date/month of service is not relevant because it serves no aid to Plaintiffs' stated ends of tying medications patients received to a potential temperature excursion on a given date. For this reason alone, Plaintiffs' argument fails.

Plaintiffs' case law fairs no better. In Sasikumar v. Brooklyn Hosp. Ctr., No. 09 CV 5632 (ENV)(RML), 2011 WL 1642585 (E.D.N.Y. May 2 2011), the party resisting production of related complaints of discrimination or retaliation argued that the requested records would be unduly burdensome because there "had been great turnover in its management" and "there was no central repository where records of all complaints are kept." Id. at *3. The court held "it would be unfair to allow it to derive a benefit from its poor recordkeeping." *Id.* Unlike *Sasikumar*, where the records that the court admonished Defendant for poorly maintaining existed, the records that Plaintiffs seek to tie together do not exist and producing date/month of service will not change that fact. Courts "cannot order the production of evidence that does not exist," and ordering production of the date/month of service will not change the irrelevancy of this information. Marco Techs., LLC v. Midkiff, No. 19-cv-2323 (PJS/LIB) 2020 WL 12442103, at *4 (D. Minn. Oct. 8, 2020). Because there are no records that would identify a particular medication being stored at a DCP location on a particular date or at a particular temperature, aside from what has already long since been produced, the date/month of service is not relevant. Sasikumar is of no assistance to this issue.

Similarly, *Cent. Ill. Carpenters Health & Welfare Tr. Fund v. Streuben* was an order entering judgment following a bench trial and did not discuss the discoverability of certain information, but rather liability in light of "failure to keep records as statutorily required." No. 05-1094, 2009 WL 497393, at *11 (C.D. Ill. Feb. 24, 2009). Nothing in *Streuben* indicates whether disclosing date/month of service in a motion to compel is proper.

With respect to Plaintiffs' argument regarding the date/month of service information going to weight, rather than relevance, *Bartis v. Biomet* concerned data that the party resisting production claimed was "unreliable." No. 4:13-cv-00657-JAR, 2021 WL 2092785, at *3 (E.D. Mo. May 24, 2021). Unsurprisingly, the court held that "[t]his argument clearly goes to admissibility and weight, not discoverability." *Id.* As argued above, the information Plaintiffs seek is not relevant because it does not enable them to identify a particular medication being stored in a DCP refrigerator on a particular date at a particular temperature. The issue here is relevance, not admissibility and weight as was the case in *Bartis*.

The arguments and cases cited by Plaintiff relating to discovery disputes concerned documents that existed and were otherwise based on arguments that Defendants do not make here. Plaintiffs' reliance on these cases is inappropriate because the information they seek—whether time- and temperature sensitive medications delivered to patients were affected by the temperature excursions—does not exist and thereby renders date/month of service information irrelevant to any claims or defenses in this lawsuit. The Court should not give this argument any credence.

III. PRODUCING UNIQUE IDENTIFIERS OR MRNs IS UNDULY BURDENSOME TO DEFENDANTS AND NOT PROPORTIONAL TO THE NEEDS OF THE CASE.

Plaintiffs next argue that Essentia should be forced to produce either patients' MRNs or otherwise substitute them with unique patient identifiers. *See* Dkt. No. 274 at 7-8. Requiring Defendants to do so is unduly burdensome and not proportional to the needs of the case.

A. Defendants are Unable to Overlay Unique Identifiers over Patient MRNs Across the Entire Document Production.

Following the Report and Recommendation of the Special Master, Plaintiffs suggested that Essentia supply a unique identifier over patients' MRNs so that they could track a patient. The parties met and conferred on this issue, and Essentia spoke with its ESI vendor about the feasibility of doing so. Essentia was informed by the ESI vendor that it does not have the technology to implement such a task and that inserting unique identifiers across the universe of document production was not possible. For Plaintiffs to now state that "Defendant has rejected this compromise" is a gross mischaracterization of the parties' conduct, as Essentia would have considered implementing this if they were capable of doing so. *Id.* at 7. The reality of the situation is that this is not something that is capable of being implemented.²

11

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² For this reason, and in light of the substantial completion of document production deadline looming, Essentia proceeded to redact patient MRNs so that these documents could be produced as soon as possible.

B. Producing MRNs is Not Proportional to the Needs of the Case in Light of Other Documents Produced in this Litigation.

Given that unique account identifiers cannot be inserted across Essentia's document production, Plaintiffs now for the first time appear to ask for purely unredacted patient MRNs. *Id.* at 7-8. Such a request is not proportional to the needs of the case in light of the financial documents and data that Essentia has already produced.

Plaintiffs—for quite some time—have been in possession of certain financial documents produced by Defendants which enable Plaintiffs to evaluate their claims and allegations.³ Included in these documents are Unique Account Numbers, year of service, type of service, CPT Codes, and financial/billing information. Essentia produced this information for every potentially impacted putative class member, and this information fully enables Plaintiffs to evaluate their claims and the financial impact the potential temperature excursions may have had on the putative class.⁴

Given that this information has already been produced, and given the fact that most documents involving MRNs have been produced in redacted form, requiring Essentia to now go back and unredact all MRNs is unduly burdensome and not proportional to the needs of the case. The time and expense involved for Essentia to do so far outweighs the

³ See, e.g., EH025384, EH025385, EH025386, EH025387, EH025388, EH025389, EH025390, EH025391.

⁴ The documents cited in footnote 3 have undergone several iterations—at the request of Plaintiffs—and are not the only documents produced relative to this data. Prior production of these financial spreadsheets included aggregate patient data such that no individual member of the putative class appeared on more than one row of any given spreadsheet. In other words, Plaintiffs have received voluminous de-identified data in multiple different formats.

benefit to Plaintiffs obtaining MRNs, as the information they seek is already in their possession, albeit in a different format. The Court should therefore not order MRNs to be disclosed, as Plaintiffs have already received putative class information in a less burdensome format which equally enables them to evaluate putative class members' damages. FED. R. CIV. P. 26(b)(2)(C)(i).

IV. HIPAA DOES NOT MANDATE DISCLOSURE OF PHI UNDER A PROTECTIVE ORDER AND PLAINTIFFS HAVE NOT DEMONSTRATED A NEED FOR OTHERWISE PROTECTED PHI.

Plaintiffs lastly argue that "HIPAA permits the disclosure of PHI" in response to a court order or discovery request so long as there is a "qualified protective order" in place. *See* Dkt. No. 274, at 8. Plaintiffs ignore the fact that HIPAA does not *require* production—only that production *may* occur—and furthermore fails to provide justification as to why they are entitled to otherwise protected PHI.

As this Court made clear several years ago, "a HIPAA qualified protective order may authorize disclosure of putative class members' PHI. HIPAA does not mandate disclosure. In each of the cases plaintiffs cite, the court balanced need for the production against other factors." See Order Regarding Discovery Disputes (Dkt. No. 76, at 10) (emphasis added). At that time, the Court also noted that Plaintiffs "have so far not sufficiently explained their need for patient-specific information regarding putative class members." Id. Plaintiffs still have not adequately explained the need for patient-specific information regarding putative class members.

With regards to date/month of service, Plaintiffs have failed to show how such information is relevant or proportional to the needs of this case given its inability to identify

a particular medication being stored at DCP location on a particular date or at a particular temperature. Similarly, obtaining MRNs of the entire putative class is unduly burdensome and not proportional to the needs of the case in light of the financial spreadsheets which outline all vaccines, medications, and financial data of the putative class. On this record, the benefit of Plaintiffs receiving patient-specific data, if any, is largely outweighed by the burden to Essentia and its patients, including the psychological cost which would be borne from such disclosure, in producing the data Plaintiffs seek. The Court should not order protected PHI information under HIPAA to be disclosed in light of Plaintiffs' failure to demonstrate their need for patient-specific information beyond what has already been produced.

CONCLUSION

For the reasons set forth above and at the October 4, 2018 status conference, the Court should not require Essentia to produce date/month of service or MRNs of the putative class. The information Plaintiffs seeks is protected by HIPAA, and Plaintiffs have failed to show a valid need in light of the balancing of factors under Fed. R. Civ. P. 26(b)(1). The Court should deny Plaintiffs' requests in their entirety.

Dated this 18th day of October, 2024.

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